BNF -

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 27 1995

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Ms. Diane Re
Regulatory Affairs
The Agricultural Group of Monsanto
700 Chesterfield Parkway North
Chesterfield, MO 63198

Dear Ms. Re:

This is in regard to your genetically modified glyphosate-tolerant soybean about which you initiated consultations with the agency in June 1993. The new soybean variety has been rendered tolerant to glyphosate by expression of a 5-enolpyruvylshikimate-3-phosphate synthase from the bacterium *Agrobacterium sp.* strain CP4.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new soybean variety on September 2, 1994. On September 19, 1994, you also made a detailed oral presentation of the data that support your submission. It is our understanding that these communications were intended by Monsanto to inform FDA of the steps taken to ensure that this product complies with the Federal Food, Drug, and Cosmetic Act. Further, it is our understanding that, based on the safety and nutritional assessment you have conducted, you have concluded that the new soybean variety is not materially different in composition, safety, or any other relevant parameter from soybean varieties currently on the market and that it does not raise issues that would require premarket review or approval. All materials relevant to this consultation have been placed in a file that has been designated BNF 0001 and that will be maintained in the Office of Premarket Approval.

Based on the description of the data and information presented during the consultations, the new soybean variety does not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2). We have no additional questions concerning this product at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition